Summary

K051841

AUG 2 2 2005

510(k) SUMMARY

Date of Summary: August 2, 2005

Product Name:
WH Accu Test™ One-Step Urine/Serum Combo Pregnancy Test

Sponsor and Manufacturer
WHPM, Inc.
9440 Telstar Avenue, Unit 1
El Monte, CA 91731

Correspondent
Fran White, President
MDC Associates, LLC
163 Cabot Street
Beverly, MA 01915

Substantially Equivalent Devices
Manufacturer: Acon Laboratories
Product: One Step Pregnancy Test (Urine/Serum) [510(k) number: K993065]

Product Description
The WH Accu Test™ One-Step Urine/Serum Combo Pregnancy Test is a lateral flow immunoassay intended for the detection of human Chorionic Gonadotropin (hCG) in urine or serum.

Intended Use
The WH Accu Test™ One-Step Urine/Serum Combo Pregnancy Test is for the qualitative determination of human chorionic gonadotropin (hCG) in urine or serum to aid in the early detection of pregnancy. For Laboratory Professional Use Only.

Summary of Technology
The WH Accu Test™ One-Step Urine/Serum Combo Pregnancy Test employs a unique combination of monoclonal-dye conjugate and polyclonal solid-phase antibodies to selectively identify human Chorionic Gonadotropin (hCG) in urine and serum. As the urine or serum sample flows through the absorbent portion of the device, the antibody-dye conjugate binds to the hCG forming an antibody-antigen complex. This complex binds to the anti-hCG antibody in the positive reaction zone and produces a pink-rose color band if hCG concentration is equal to or greater than 25 mIU/mL. In the absence of hCG, there is no line in the reaction zone. Unbound conjugate binds to the reagents in the control zone, producing a pink-rose color band, demonstrating that the reagents are functioning correctly.

Performance Data
A method comparison study was done to compare the performance of the WH Accu

Test™ Pregnancy Test. These data clearly demonstrate the performance of the product manufactured by WHPM is substantially equivalent to the Acon Laboratories hCG One Step Pregnancy Test (Urine/Serum). 100% agreement was observed.

Agreement =	100%

Statement of Safety and Efficacy

The WH Accu Test™ One Step Pregnancy Test when compared with another commonly used pregnancy test (Acon Laboratories hCG One Step Pregnancy Test) demonstrated 100% performance.

These data clearly demonstrate the safety and efficacy of the WH Accu Test™ One Step Pregnancy Test and further confirms the accuracy of the product when compared to a substantially equivalent device currently being sold for professional use. Testing was done by a person who routinely performs pregnancy tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 2 2 2005

WHPM, Inc.
c/o Ms. Fran White
Regulatory Consultant
MDC Associates, LLC
163 Cabot Street
Beverly, Massachusetts 01915

Re: k051841
Trade/Device Name: WH Accu Test™ One-Step Urine/Serum Combo Pregnancy Test
Regulation Number: 21 CFR § 862.1155
Regulation Name: Human chorionic gonadotropin test system
Regulatory Class: II
Product Code: JHI
Dated: August 4, 2005
Received: August 5, 2005

Dear Ms. White:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051841/S1

Device Name: WH Accu Test One Step Urine/Serum Combo Pregnancy Test

Indications For Use:

The WH Accu Test™ One-Step Urine/Serum Combo Pregnancy Test is a test for the qualitative determination of human chorionic gonadotropin (hCG) in urine or serum to aid in the early detection of pregnancy. For Laboratory Professional Use Only.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K051841